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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Status of Claims

1. This action is in reply to the amendment filed on 02 October 2008.

2. Claims 1-3, 6-7, 9-13 & 15-17 have been amended.

3. Claims 4 and 21 have been canceled

4. Claims 1-3, 5-20, & 22-24 are currently pending and have been examined.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. The previous 35 U.S.C. 101 rejection of claims 1-3,6-7,9-13, & 15-17 does not apply in light of Applicant's amendments. In response to Applicant's amendment, there is a new 35 U.S.C. 101 issue.

7. Claims 1-3 & 5-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The limitations of claims 1 and 12 are data structures that are not claimed as embodied in computer-readable media, and therefore are not statutory because they are not capable of causing functional changes in the computer. Such claimed data structures do not define any structural and functional interrelationships between the data structure and other claimed aspects of the invention which permit the data structure's functionality to be realized.

Dependent claims 2-3, 5-11 & 13-17 fail to cure this deficiency of claims 1 & 12, and thus are rejected on the same grounds. When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material, i.e., abstract ideas, stored on a computer-readable medium, in a computer, or on an electromagnetic carrier signal, does not make it statutory. See >*Diamond v.*< *Diehr*, 450 U.S. *>175,< 185-86, 209 USPQ *>1,< 8 (noting that the claims for an algorithm in *Benson* were unpatentable as abstract ideas because "[t]he sole practical application of the algorithm was in connection with the programming of a general purpose computer."). Such a result would exalt form over substance. *In re Sarkar,* 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978) ("[E]ach invention must be evaluated as claimed; yet semantogenic considerations preclude a determination based solely on words appearing in the claims. In the final analysis under § 101, the claimed invention, as a whole, must be evaluated for what it is.") (quoted with approval in *Abele*, 684 F.2d at 907, 214 USPQ at 687). See also *In re Johnson*, 589 F.2d 1070, 1077, 200 USPQ 199, 206 (CCPA 1978) ("form of the claim is often an exercise in drafting"). Thus, nonstatutory music is not a computer component, and it does not become statutory by merely recording it on a compact disk. Protection for this type of work is provided under the copyright law. When nonfunctional descriptive material is recorded on

some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory and should be rejected under 35 U.S.C. 101. In addition, USPTO personnel should inquire whether there should be a rejection under 35 U.S.C. 102 or 103. USPTO personnel should determine whether the claimed nonfunctional descriptive material be given patentable weight. USPTO personnel must consider all claim limitations when determining patentability of an invention over the prior art. *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 403-04 (Fed. Cir. 1983). USPTO personnel may not disregard claim limitations comprised of printed matter. See *Gulack*, 703 F.2d at 1384, 217 USPQ at 403; see also *Diehr*, 450 U.S. at 191, 209 USPQ at 10. However, USPTO personnel need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See ** *Lowry*, 32 F.3d **>at< 1583-84, 32 USPQ2d **>at< 1035 **; *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004). (MPEP § 2106.01)

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

    1. Determining the scope and contents of the prior art.
    2. Ascertaining the differences between the prior art and the claims at issue.
    3. Resolving the level of ordinary skill in the pertinent art.
    4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-3, 5-20, & 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0099302) (hereinafter Bardy) in view of Pence et al. (US 5978751) (hereinafter Pence).

11. **Examiner's Note**: The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

Claim 1

Bardy as shown, discloses the following limitations:

*   *accessing a trial database comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;* (see at least Bardy [0008] & [0009])

- *performing a statistical analysis on the accessed trial database without suspending the ongoing blinded clinical trial*; (see at least Bardy [0009], [0037], Fig:5 Items:16, 125-134 & related text)

- *determining whether the result of the statistical analysis exceeds a predetermined threshold value*; (see at least Bardy [0059])

- *accessing a blinding database comprising subject identifiers and associated study group identifiers, wherein a subject's study group being identifiable by a study group identifier;* (see at least Bardy [0011], [0035], [0037] Fig:2-4 Items:40-73, 80-91, 95-111 & related text)

- *generating a grouped database from the trial database and the blinding database for statistical analysis, the grouped database grouping the trial data of the subjects based on their study group;* (see at least Bardy [0033], [0035], [0043-44], Fig.5 Items:26,27,125,129-133 & related text)

Bardy does not disclose the following limitations, however Pence, as shown, does:

- *if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then repeating said computer-executable instructions for accessing a trial database, performing and determining while the blinded clinical trial is ongoing;* (see at least Pence Column:5 Lines:30-46, Fig. 2 Items:50, 52 "Detail 'A'" & related text)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy. One of ordinary skill in the art would have

added this feature into Bardy with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system.

Claim 2

The combination of Bardy/Pence discloses all the limitations of Claim 1. Bardy further discloses the following limitations:

- *reading a user defined criteria that defines the level of cleanliness of the trial data for statistical analysis*; (see at least Bardy [0048])

- *retrieving only those trial data that meet the user defined criteria from the trial database* (see at least Bardy [0011])

Claim 3

The combination of Bardy/Pence discloses all the limitations of Claim 1. Pence further discloses the following limitation:

- *computer-executable instruction for waiting for a predetermined time period prior to the repeating said computer-executable instruction for accessing a trial database, performing and determining while the blinded clinical trial is ongoing if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value;* (see at least Pence Fig. 2 Items:50,51,52 & "Detail 'A'")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system.

Claim 5

The combination of Bardy/Pence discloses all the limitations of Claim 1. Pence further discloses the following limitation:

- *computer-executable instruction for storing the grouped database in a memory device that is inaccessible by any user* (see at least Pence Column:5 Lines:47-51)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system.

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure that the integrity of the database is maintained.

Claim 6

The combination of Bardy/Pence discloses all the limitations of Claim 1. Bardy further discloses the following limitation:

- *computer-executable instruction for performing a statistical analysis is executed without locking the trial database* (see at least Bardy [0048])

Claim 7

The combination of Bardy/Pence discloses all the limitations of Claim 1. Bardy further discloses the following limitation:

- *reading a predefined criteria that defines the level of cleanliness of trial data required for analysis*; (see at least Bardy [0048])

- *retrieving only those trial data that meet the predefined criteria from the trial database*; (see at least Bardy [0011])

Claim 8

The combination of Bardy/Pence discloses all the limitations of Claim 7. Bardy further discloses the following limitation:

- *ongoing blinded clinical trial;* (see at least Bardy [0008])

Bardy does not disclose the following limitations, however Pence, as shown, does:

- *computer-executable instruction for storing the grouped database in a memory device that is inaccessible by any user to preserve the blindness of the clinical trial;* (see at least Pence Column:5 Lines:47-51)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would

have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure the integrity of the database is maintained.

Claim 9

The combination of Bardy/Pence discloses all the limitations of Claim 1. Bardy further discloses the following limitation:

- *computer-executable instruction for alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value.* (see at least Bardy Fig. 5 Item:127 and [0041])

Claim 10

The combination of Bardy/Pence discloses all the limitations of Claim 9. Pence further discloses the following limitation:

- *wherein the predetermined threshold value includes a predetermined statistical significance value* (see at least Pence Column:7 Lines:28-31)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient

approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

Claim 11

The combination of Bardy/Pence discloses all the limitations of Claim 10. Pence further discloses the following limitation:

- *retrieving a user defined statistical model; and running the retrieved user defined statistical model on the trial database.* (see at least Pence Column:7 Lines:28-31)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

Claim 12

Bardy as shown, discloses the following limitations:

- *accessing a trial database comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;* (see at least Bardy [0008] & [0009])

- *performing a statistical analysis on the accessed trial database without suspending the ongoing blinded clinical trial;* (see at least Bardy [0009], [0037], Fig:5 Items:16, 125-134 & related text)

- *accessing a blinding database containing subject identifiers and associated study group identifiers, each study group identifier identifying to which study group an associated subject belongs;* (see at least Bardy [0037])

- *producing a grouped database from the trial database and the blinding database, the grouped database grouping the trial data according to the study group;* (see at least Bardy Fig.5 Items:26,27,125,129-133)

- *determining whether the result of the statistical analysis exceeds a predetermined threshold value*; (see at least Bardy [0059])

Bardy does not disclose the following limitation, however Pence, as shown does:

- *if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then repeating said computer-executable instruction for accessing a trial database, performing and determining while the blinded clinical trial is ongoing;* (see at least Pence Fig. 2 Items:50, 52 & "Detail 'A'")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy. One of ordinary skill in the art would have added this feature into Bardy with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system.

Claim 13

The combination of Bardy/Pence discloses all the limitations of Claim 12. Bardy further discloses the following limitations:

- *reading a user defined criteria that defines the level of cleanliness of trial data for statistical analysis*; and(see at least Bardy [0048])

- *retrieving only those trial data that meet the user defined criteria from the trial database for statistical analysis.* (see at least Bardy [0011])

Claim 14

The combination of Bardy/Pence discloses all the limitations of Claim 12. Pence further discloses the following limitations:

- *computer-executable instruction for storing the produced grouped database in a memory device that is inaccessible by any user* (see at least Pence Column:5 Lines:47-51)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure the integrity of the database is maintained.

Claim 15

The combination of Bardy/Pence discloses all the limitations of Claim 12. Bardy further discloses the following limitations:

- *computer-executable instruction for performing a statistical analysis is executed without locking the trial database.* (see at least Bardy [0048])

Claim 16

The combination of Bardy/Pence discloses all the limitations of Claim 12. Bardy further discloses the following limitations:

- *computer-executable instruction for alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value.* (see at least Bardy Fig. 5 Item:127 and [0041])

Claim 17

The combination of Bardy/Pence discloses all the limitations of Claim 16. Pence further discloses the following limitations:

- *wherein the predetermined threshold value includes a predetermined statistical significance value.* (see at least Pence Column:7 Lines28-31)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

Claim 18

Bardy as shown, discloses the following limitations:

- *a storage device operable to store a trial database comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;* (see at least Bardy [0035])

- *a processor coupled to the storage device;* (see at least Bardy Fig. 1 Items14,16-18)

- *an analysis program executable by the processor* (see at least Bardy Fig. 5 Items16,131)

- *access the trial database to retrieve the trial data;* (see at least Bardy [0037] & [0043])

- *accessing a blinding database comprising subject identifiers and associated study group identifiers, wherein a subject's study group being identifiable by a study group identifier;* (see at least Bardy [0011], [0035] & [0037])

- *generating a grouped database from the trial database and the blinding database for statistical analysis, the grouped database grouping the trial data of the subjects based on their study group;* (see at least Bardy [0033], [0035] Fig.5 Items:26,27,125,129-133 & related text)

- *performing a statistical analysis on the accessed trial database without suspending the ongoing blinded clinical trial;* (see at least Bardy [0009], [0037], Fig:5 Items:16, 125-134 & related text)

- *determine whether the output result of the statistical analysis exceeds a predetermined threshold value;* (see at least Bardy [0059])

Bardy does not disclose the following limitation, however Pence, as shown does:

- *repeat the statistical analysis while the blinded clinical trial is ongoing if it is determined that the result of the statistical analysis does not exceed the*

predetermined threshold value (see at least Pence Column:5 Lines:30-46, Fig. 2

Items:50, 52 "Detail 'A'" & related text)

It would have been obvious to one of ordinary skill in the art at the time of the invention

to combine the feature of Pence into Bardy. One of ordinary skill in the art would have

added this feature into Bardy with the motivation of providing a more efficient and

systematic approach to detecting trends in continuously collected data indicative of the

progression or regression from the user defined threshold value, using an automated

method and system.

Claim 19

The combination of Bardy/Pence discloses all the limitations of Claim 18. Bardy further

discloses the following limitations:

- *read a user defined criteria that defines the level of cleanliness of trial data for statistical analysis*; (see at least Bardy [0048])

- *retrieve only those trial data that meet the user defined criteria from the trial database* (see at least Bardy [0011])

Claim 20

The combination of Bardy/Pence discloses all the limitations of Claim 18. Pence further

discloses the following limitations:

- *wherein if the analysis program determines that the result of the statistical analysis does not exceed the predetermined threshold value, then the analysis program waits*

for a predetermined time period prior to repeating the statistical analysis. (see at least Pence Fig. 2 Items:50,51,52 & "Detail 'A'")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

Claim 22

The combination of Bardy/Pence discloses all the limitations of Claim 18. Pence further discloses the following limitation:

- *a memory device coupled to the processor* (see at least Pence Fig. 1 Items:11,15 and related text).

- *being inaccessible to any user, wherein the grouped database is stored only in the memory device.* (see at least Pence Column:5 Lines:47-51)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure the integrity of the database is maintained.

Claim 23

The combination of Bardy/Pence discloses all the limitations of Claim 18. Bardy further discloses the following limitation:

- *wherein the analysis program performs the statistical analysis without locking the trial database* (see at least Bardy [0048])

Claim 24

The combination of Bardy/Pence discloses all the limitations of Claim 18. Bardy further discloses the following limitation:

- *wherein the analysis program is further operable to alert a user if it determines that the result of the statistical analysis exceeds the predetermined threshold value* (see at least Bardy [0059])

Response to Arguments

10. Applicant's arguments received on 02 October 2008 have been fully considered but they are not persuasive. Applicants' arguments will be addressed herein below in the order in which they appear in the response filed 02 October 2008.

11. Applicant appears to argue that the prior art fails to teach *blinded clinical trials*. However, Examiner notes that this aspect of the limitations fails to make the

invention patentable, as this concept is already known in the art. (see at least Applicant's Own Admission [0008]) Further, Applicant's claim language: *blinded clinical trials;* is merely a recitation of the intended use of the claimed invention and is not given patentable weight to the extent that it imparts limitations to the invention, which are met by Bardy/Pence. (See MPEP 2111.04) A recitation of the intended use of the claimed invention must result in a substantial difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, then it meets the claim.

12. Applicant argues that the cited prior art are not directed towards the same purpose as the applicant's invention. Examiner points out that it is not necessary for the prior art to have an identical purpose to that of Applicant's invention. In addition, Examiner points out that all the cited prior art do teach or suggest the limitations of Applicant's invention.

13. Applicant appears to argue that the prior art fails to teach *clinical trials*. However, Examiner notes that this aspect of the limitations fails to make the invention patentable. While the prior art may no have an intended use for *clinical trials*, the prior art clearly does disclose the limitations of the Examiner's application. The teachings of the prior art specifically disclose the ideas and concepts disclosed in Applicant's limitations. Further, Applicant's claim language: *clinical trials;* is merely a recitation of the intended use of the claimed invention and is not given patentable

weight to the extent that it imparts limitations to the invention, which are met by Bardy/Pence. (See MPEP 2111.04) A recitation of the intended use of the claimed invention must result in a substantial difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, then it meets the claim.

14. Applicant argues that Brady/Pence fail to teach or suggest *accessing a blinding database comprising subject identifiers and associated study group identifiers.* Examiner respectfully disagrees. In addition the cited prior art, Examiner specifically points to the lines of Bardy [0035] "*Each patient care record 23 contains normal patient identification and treatment profile information, as well as medical history, medications taken, height and weight, and other pertinent data . . . "* combined with the other cited prior art clearly suggest and teaches this limitation. The measurement *identification and treatment profile information*, is an example of the *identifiers*, stated in applicant's limitation.

15. Applicant argues that Brady/Pence fail to teach or suggest *generating a grouped database from the trial database and the blinding database.* Examiner respectfully disagrees. In addition the cited prior art, Examiner specifically points to Fig.5 of Bardy, which clearly shows items 16 & 125 as a *grouped database*, which is generated from database items 26 & 27. This section of the cited prior art illustrates a teaching or suggestion of this claim language. The fact that these databases are

trial & *blinded* has been addressed above, and does not further affect the metes and bounds of this limitation.

16. Applicant argues that Brady/Pence fail to teach or suggest *performing a statistical analysis on the accessed trial database without suspending the ongoing blinded clinical trial.* Examiner respectfully disagrees. Examiner points out that the *statistical analysis* is done away from the *clinical trial* and is not directly affected by the databases. In addition the *trial* & *blinded* databases, which has been dealt with in previous arguments, and are a mere matter of design choice or choice in ornamentality and produces no new mechanical effect or advantage does not constitute invention and "Counsel for appellant also present arguments relating to the proportioning and tightness of fit of appellant's devices. Those matters are considered to involve mechanical skill only and to produce no such new or unexpected result as would justify the allowance of the appealed claims." See, *In re Seid,* 161 F.2d 229, 231, 73

17. Applicant argues that Brady/Pence fail to teach or suggest *determining whether the result of the statistical analysis exceeds a predetermined threshold value.* Examiner respectfully disagrees. The cited prior art teaches and suggests the determination of values in relation to a threshold value. In addition the Applicant argues that the cited prior art does not teach or suggest the *blindness* of the trials. This matter is dealt with in previous arguments, and does not affect the applicability of the cited prior art on the metes and bounds of this claim language. Further, the *blindness* is a mere

matter of choice in ornamentality and produces no new mechanical effect or advantage does not constitute invention and "Counsel for appellant also present arguments relating to the proportioning and tightness of fit of appellant's devices. Those matters are considered to involve mechanical skill only and to produce no such new or unexpected result as would justify the allowance of the appealed claims." See, *In re Seid,* 161 F.2d 229, 231, 73

18. Applicant argues that Brady/Pence fail to teach or suggest *repeating the steps of accessing, performing and determining while the blinded clinical trial is ongoing.* Examiner respectfully disagrees. In addition the cited prior art, Examiner specifically points to Fig.2 Items:51, 52, Detail "A" of Pence, which clearly illustrates prior art capable of *repeating the steps of accessing, performing and determining while the blinded clinical trial is ongoing.*

19. Applicant argues that Brady/Pence fail to teach or suggest *reading a user defined criteria that defines the level of cleanliness of the trial data for statistical analysis; and retrieving only those trial data that meet the user defined criteria from the trial database"*. Examiner respectfully disagrees. In addition the cited prior art, Examiner specifically points to the lines of Bardy [0011] "A plurality of monitoring sets is retrieved from a database. Each monitoring set includes recorded measures that each relates to patient information" and Bardy [0048] "In addition, the feedback module 128 determines whether any changes to interventive measures are appropriate based on threshold stickiness ("hysteresis") 133, as further described

below with reference to FIG. 16. The threshold stickiness 133 can prevent fickleness in diagnostic routines resulting from transient, non-trending and nonsignificant fluctuations in the various collected and derived measures in favor of more certainty in diagnosis", which clearly illustrates prior art capable of *reading a user defined criteria that defines the level of cleanliness of the trial data for statistical analysis; and retrieving only those trial data that meet the user defined criteria from the trial database.*

20. Applicant argues that Brady/Pence fail to teach or suggest *waiting for a predetermined time period prior to the repeating step if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value"*. Examiner respectfully disagrees. In addition the cited prior art, Examiner specifically points out that the issue of a *repeating step* is dealt with above. As per applicant's request for "Examiner to identify where Pence" teaches this limitation, Examiner points to Fig:2 Items:50-52 which shows repeating, and the *waiting for a predetermined time period* is taught by Item:51, which teaches waiting for a determined set of time, and covers the metes and bounds of this claim language.

21. Applicant argues that Brady/Pence fail to teach or suggest *storing the grouped database in a memory device that is inaccessible by any user.* Examiner respectfully disagrees. In addition the cited prior art, Examiner specifically points to Pence Column:5 Lines:47-51, as also cited by Applicant. While the applicant argues that the prior art does present an invention that is capable of be accessible, the

Examiner points out that the cited prior art also teaches an invention capable of *storing the grouped database in a memory device that is <u>inaccessible</u> by any user*.

22. As per claims 6, 15 and 23 applicant makes the same general arguments above, and are rejected for on the same grounds.

23. Applicant argues that Brady/Pence fail to teach or suggest *alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value.* Examiner respectfully disagrees. In addition the cited prior art, Examiner specifically points to Bardy Fig:5 Item:127, which Applicant acknowledges is a "patient status indicator". Examiner points out that a "patient status indicator" is an invention capable and synonymous with an invention that "alerts a user".

24. In response to Applicant's remaining arguments, it is respectfully submitted that the Examiner has applied prior art to amended and original claims 1-3, 5-20, & 22-24. The Examiner notes that the amended claims were not in the previously pending claims as such, Applicant's additional remarks with regard to the applications of the prior art used in the first Non-Final Office Actions to the amended claims are moot in light of the cited prior art references as disclosed above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Rajiv J. Raj** whose telephone number is **(571) 270-3930.** The Examiner can normally be reached on Monday-Friday, 7:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **Jerry O'Connor** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair <http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

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